

Figures

Figure 1

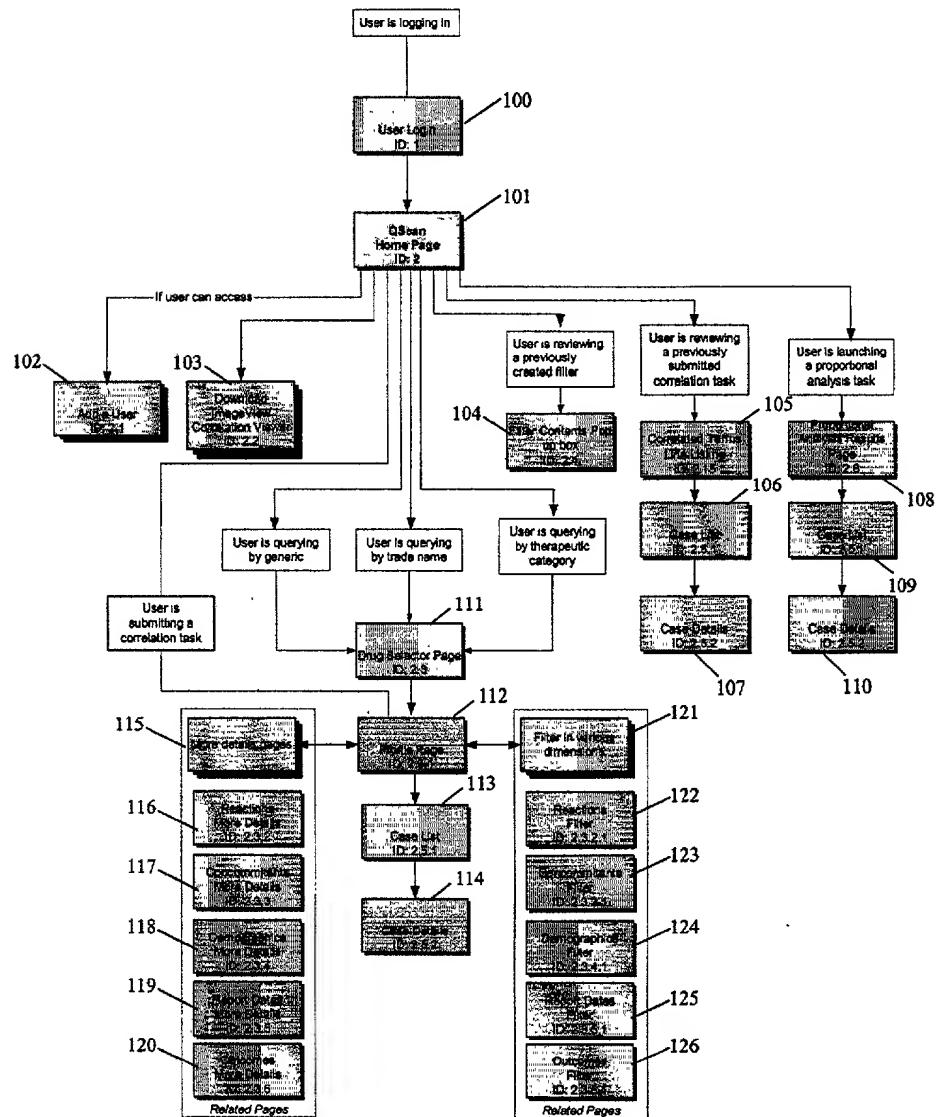


Figure 2

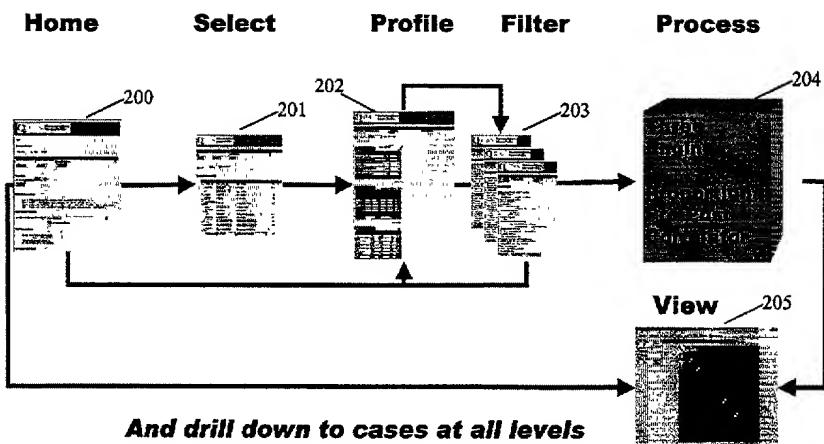


Figure 3

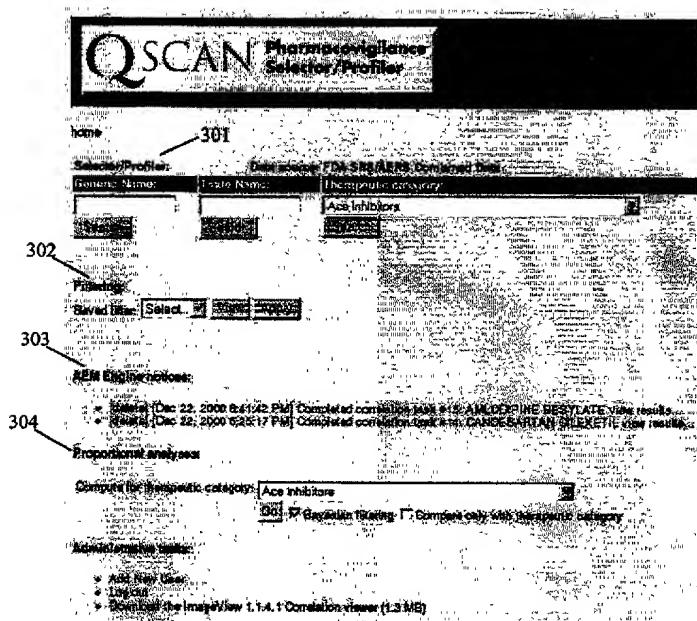


Figure 4

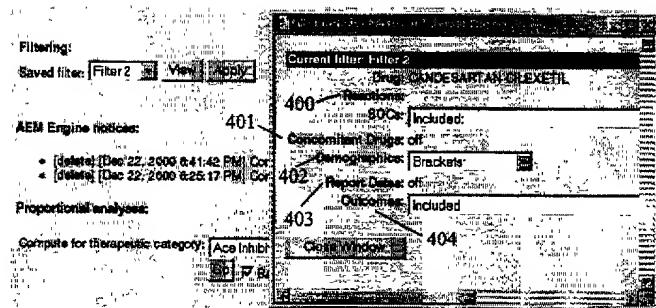


Figure 5

home > drug selector

500 Selected/Profil/eff.

501 Date source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

502 Ace Inhibitors

Filtering: Saved filter [Select] [View] [Delete]

22 drugs in category: ACE INHIBITORS

Generic Name	Trade Names	Therapeutic Categories	Pediatric
AMLODIPINE BESYLATE	AMLODIPINE	ACE Inhibitors	?
BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL	ACE Inhibitors	?
CANDESARTAN CILEXETIL	ATACAND	ACE Inhibitors	?
CAPTOPRIL	ACE-HEMMER	ACE Inhibitors	?
ENALAPRIL MALEATE	ACETENSIL	ACE Inhibitors	?

Figure 6

Data Pedigree		601	602	603	604	605	606	607
Map To	Verbatim	Source	Incidents	Case Count	OEDRx Processing	Cross-reference	First/Last Reported Reactions	
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1969/Dec 2 1997	
PROZAC	Prozac	AERS	3378	3308 S		Orange Book	Nov 1 1997/Jun 29 1999	
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCD Tradename	Jan 1 1979/Oct 14 1997	
FLUOXETINE	Fluoxetine	AERS	574	571 S		NDCD Tradename	Nov 1 1997/Jun 18 1999	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378	M	Orange Book	Nov 1 1997/Jun 12 1999	
PROZAC	Prozac (Fluoxetine)	AERS	140	140	M	Orange Book	Nov 7 1997/Mar 24 1999	
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122 S		Orange Book	Nov 14 1997/Jun 27 1999	
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	65	65	M	Orange Book	Mar 1 1998/Jun 24 1999	
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998	
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20	M	Orange Book	Nov 1 1997/Mar 12 1999	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17	M	Orange Book		
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15	M	Orange Book	Nov 15 1997/Jun 6 1999	

09661635 052031

Figure 7

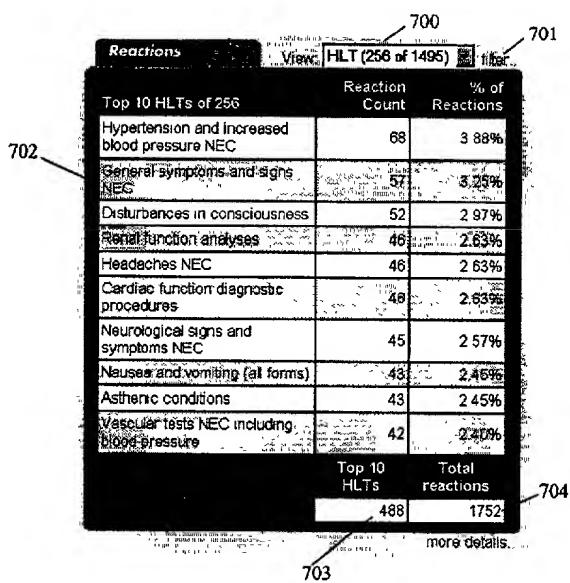


Figure 8

Concomitant Drugs

	Non-Suspect					suspect	
	S	NS	S	NS	Total	%	
Top 10 drugs							
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%	
ASPIRIN	2	38	0	5	45	10.79%	
FUROSEMIDE	2	32	0	1	35	8.39%	
DIGOXIN	0	30	0	0	30	7.19%	
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%	
ENALAPRIL MALEATE	4	15	0	5	24	5.70%	
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%	
ESTROGENS CONJUGATED	0	23	0	0	23	5.52%	
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%	
METOPROLOL TARTRATE	0	15	0	7	22	5.28%	
	Non-Suspect						
	suspect						
	Total	Total	Total	Total	Total		
	172	1141	1313				

Figure 9

900 **Demographics** 901

filter

Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
54-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

Figure 10

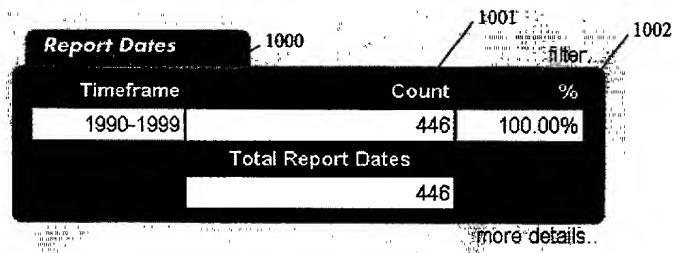


Figure 11

The screenshot shows a software interface with a table titled "Outcomes". The table has three columns: "Outcome", "Count", and "%". The data is as follows:

Outcome	Count	%
DEATH	36	7.19%
DISABILITY	18	3.59%
HOSPITALIZATION - INITIAL OR PROLONGED	231	46.11%
LIFE-THREATENING	45	8.18%
OTHER	168	33.53%
REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE	21	0.40%
Total serious outcomes	333	
Total non-serious outcomes	168	
Total outcomes	501	

Figure 12

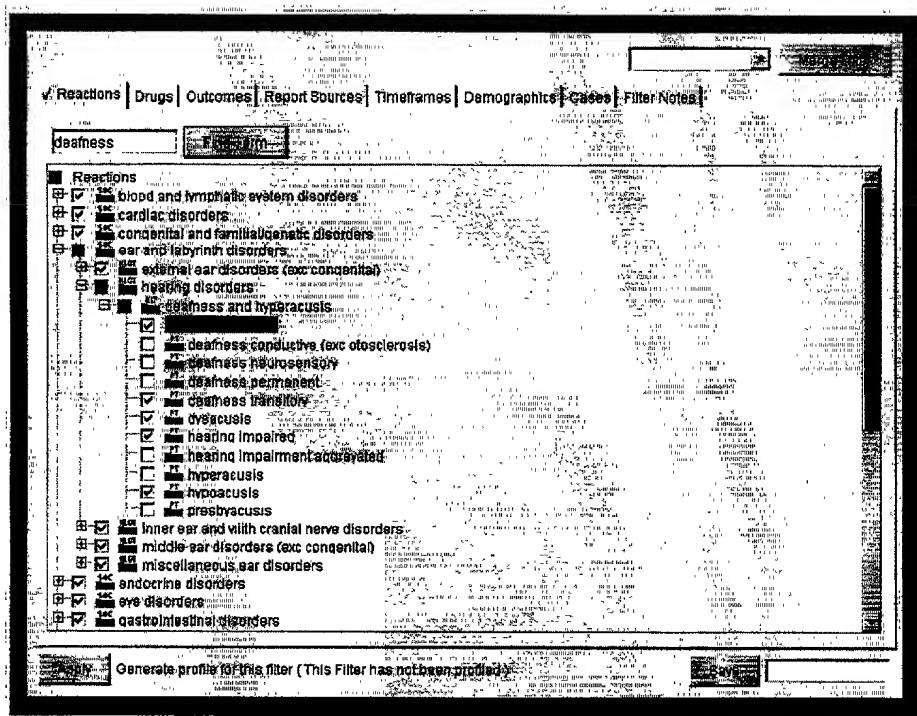


Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Page 85). View with ImageView

1303	1304	1300	1305	1302	1306
Correlated Terms				[Category]	
[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7681	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc congenital and cranial nerve)	Other Reaction	Central nervous system haemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
6	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5888	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

Figure 14

Correlation Details:
Analyzed Drug: CANDESARTAN CILEXETIL
Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1401 Cases 1 to 16 of 16 cases 1402 1403 1404 1405 1406 1407 1408

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	S	19990200143	1999-03-12	57	Acuretic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbansin Expectorante	Blood Creatinine Increased; Blood Urea Increased; Hypotension; Nausea; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Claritin, Antivert, Pyndium, Zoloft, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased, Coronary Artery Disease Nos, Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400499	1999-06-26	75	Atacand, Hydrochlorothiazide	Arrhythmia; Atrioventricular Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiograph-Segment Depression; Electrocardiogram-U Wave Abundance; Electrolyte Imbalance; Hypoglycaemia; Hypokalaemia; Hyponatraemia; Loss Of Consciousness Nos; Renal Impairment Nos; Syncope	N

Figure 15

Correlation Details					
Analyzed Drug: CANDESARTAN CIDEXETIL					
Case for term pair: Renal function/analyses [Other Reaction] / Renal failure/end-impairment [Other Reaction]					
1501	Case ID:	3198047			
1502	Sex:	F			
1503	Age:	57.0 years, 0.0 months			
1504	Reactions	As-Reported Preferred Term	High Level Term	High Level Group Term	System Organ Class
		Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations
		Hypertension NOS Hypertension NOS	Hypertension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders
		Renal Failure Renal Failure	Renal failure and impairment	Renal disorders (exc nephropathies)	Renal and urinary disorders
1505	Concomitant Drugs:	Name	Dose	Route	Support Status
		Acetaminophen	TAB QD		Yes
		Atorvastatin			No
		Atacand	16 MG QD PO ORAL		Yes
		Cefotaxime			No
		Nitro-Dur			No
		Torbasin Expectorante			No
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HO) LIFE-THREATENING(LT)			
1507	Manufacturer Control Code:	19990200143			
1508	Manufacturer Date:	1999-03-5			
1509	Adverse Event Date:	1998-12-13			
1510	Report Type:	EXP			
1511	Report Source:	OTH			
1512	Case Source:	AERS			
1513	Narrative:				

Figure 16

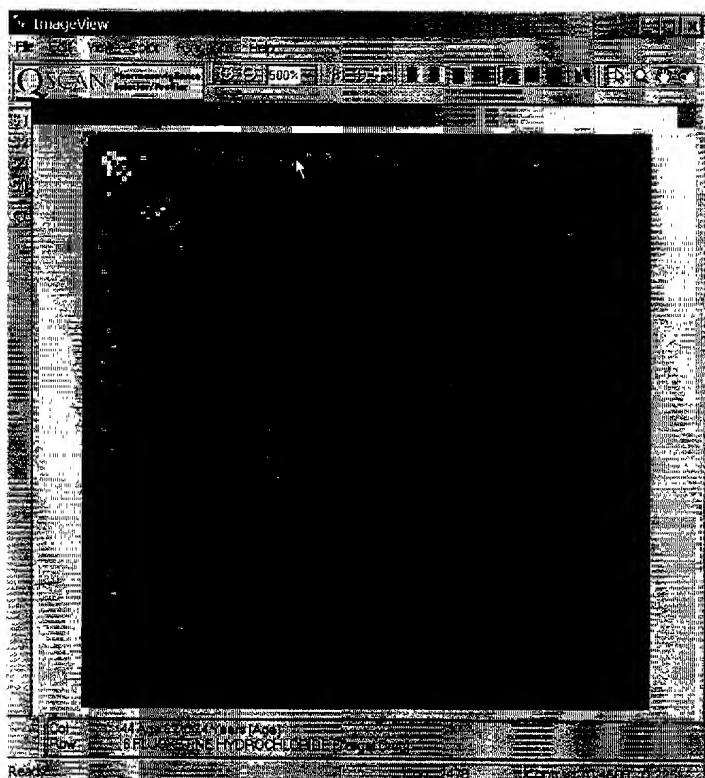


Figure 17

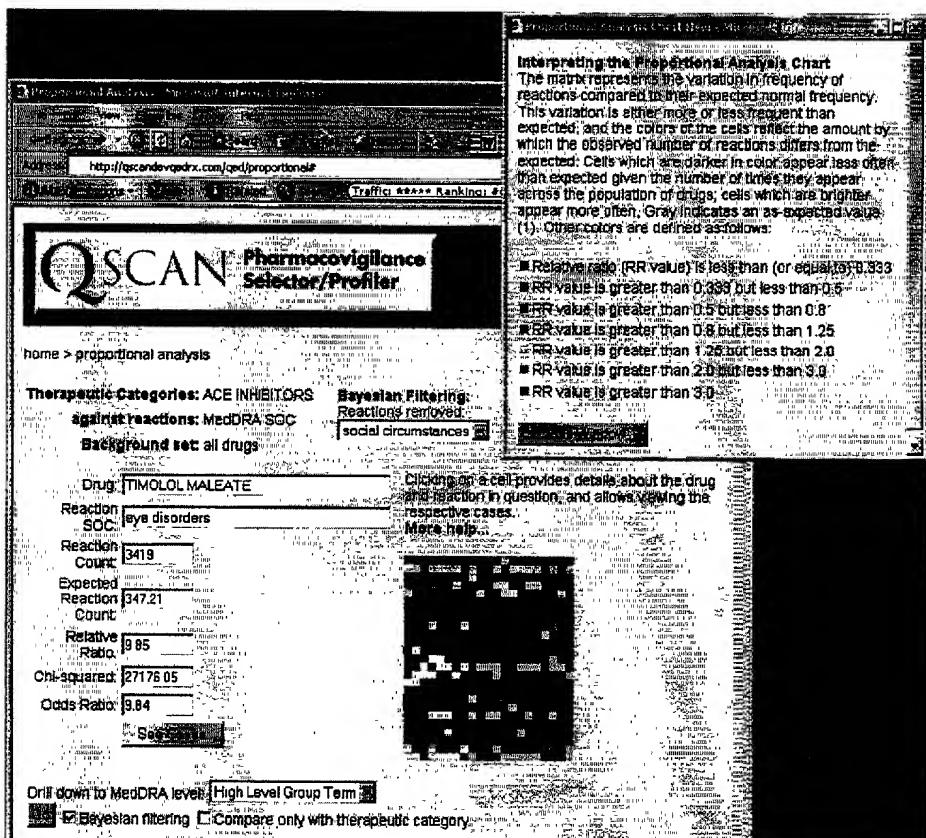


Figure 18

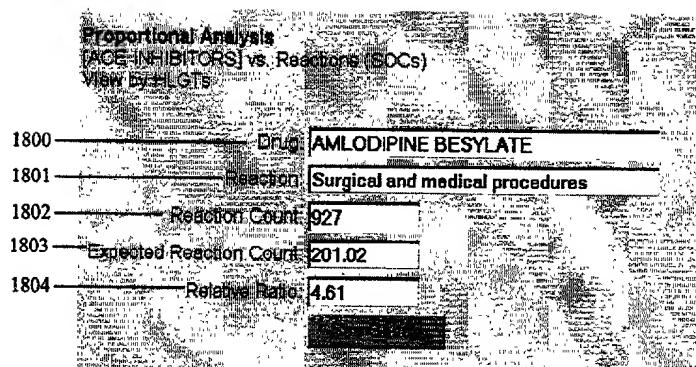


Figure 19

550 entries for this analysis are displayed below.					
Correlated Terms	1900	1901	1902	1903	1904
[Reaction]	[Drug]	[Count]	[Expected Count]	[Relative Count]	[Ratio]
1 6: Eye disorders	19: TIMOLOL MALEATE	3392	3463	9.8	
2 24: Surgical and medical procedures	2: AVLOCOPRENEBESYLATE	1732	2004	8.6	
3 14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE	838	266.5	3.1	
4 24: Surgical and medical procedures	13: METYLDOPA	57	15.6	2.4	
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE	65	28.6	2.3	
6 24: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL	32	143	2.2	
7 24: Surgical and medical procedures	20: TRANDOLAPRIL	13	6	2.2	
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE	1330	616.1	2.2	

Figure 20

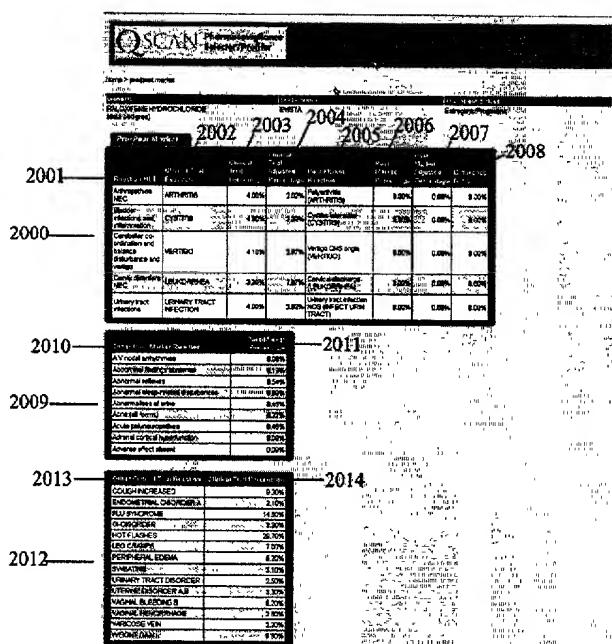


Figure 21

Drug: BENZEPHOL HYDROCHLORIDE
Reactions: SOC: Included
- Concomitant Drugs
- Demographic of Report Patients
- Report Details
- Outcome

Summary View: Cases (46 of 268 cases)
6 pages: 2101 2102 2103 2104 2105 2106 2107

2100	[Case ID]	[Sex]	[Manufacturer Control Code]	[IRIS Report Receipt Date]	[Age]	Drugs	Reactions	[Series]
1	3510123	F	200010174BBE	2000-06-1		Tylenol, Albuterol, Duraless G Prn, Aspirin, Asulamethoxo Ex Bid, Astelin, Lotemax, Zyrtec, Celebrex, Benadryl, Prostam, Lexot, Motz 25 Mg, Hydrocodone, Sustained Ativan, Zolpidem, Gantanol N 10% - Placebo, Iodine, Xylocaine, Claritin, Glycerine, Methylprednisolone, Nasores, Singulair, Phisus, Oxygen, Paxil, Salmecon Pack, Razulin 200 Mg Am	Cardiac Murmur NOS; Dyspnoea, Dyspnoea NOS, Oedema, Lower Limb, Pain In Limb, Phlebitis NOS, Physical Examination NOS Abnormal, Rhombopharyngeal Tenderness NOS, Venous Thrombosis Deep Limb	Y
2	CD1979033	F	9715410861	1997-02-26		LOTENSIN	Hypertension NOS, Tachycardia NOS	N
3	3204965	F	92061673	1999-06-26		Aspirin Coated, Lotensin, Niaspan	Athrosis, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain NOS	Y
4	CD1455473	F	833544001	1994-05-26		LOTENSIN	Hypertension, Visual Distortion	N